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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Comments on Issues of Privacy and Access With Regard to Human Genome

Sequence Data

AGENCY: Department of Health and Human Services, Office of the Secretary, The Presidential Commission for the Study of Bioethical Issues.

ACTION: Notice.

SUMMARY: The Presidential Commission for the Study of Bioethical Issues is requesting public comment on the ethical issues raised by the ready availability of large-scale human genome sequence data, with regard to privacy and data access and the balancing of individual and societal interests.

DATES: To assure consideration, comments must be received by May 25, 2012. Comments received after this date will be considered only as time permits.

ADDRESSES: Individuals, groups, and organizations interested in commenting on this topic may submit comments by e-mail to info@bioethics.gov or by mail to the following address: Public Commentary, The Presidential Commission for the Study of Bioethical Issues, 1425 New York Ave. NW, Suite C-100, Washington, DC 20005.

FOR FURTHER INFORMATION CONTACT: Cary Scheiderer, Senior Policy and Research Analyst, The Presidential Commission for the Study of Bioethical Issues, 1425 New York Avenue, NW, Suite C-100, Washington, DC 20005. Telephone: 202-233-3960. E-mail: cary.scheiderer@bioethics.gov. Additional information may be obtained at <http://www.bioethics.gov>.

SUPPLEMENTARY INFORMATION: On November 24, 2009, the President established The Presidential Commission for the Study of Bioethical Issues (Commission) to advise him on bioethical issues generated by novel and emerging research in biomedicine and related areas of science and technology. The Commission is charged to identify and promote policies and practices that assure ethically responsible conduct of scientific research and healthcare delivery. Undertaking these duties, the Commission seeks to identify and examine specific bioethical, legal, and social issues related to potential scientific and technological advances; examine diverse perspectives and possibilities for international collaboration on these issues; and recommend legal, regulatory, or policy actions as appropriate.

The Commission is examining issues of privacy and access as pertains to large-scale human genome sequence data, including whole exome and whole genome data. As a result of the tremendous technological advances that have dramatically reduced the cost of sequencing, the science is at a point where relatively inexpensive, rapid sequencing of whole human genomes appears not only likely, but imminent. This prospect raises many questions for the scientific, medical, ethics, and patient communities related to how this information can and ought be

collected, used, and governed. At the February 2012 meeting, the Commission decided to focus specifically on those questions related to privacy and data access and the balancing of individual and societal interests.

The Commission will spend the next six months soliciting additional input from the scientific, ethics, and patient communities, as well as others, to help inform our deliberations of these important topics. The Commission will provide the President with a report of its findings and recommendations later this year.

The Commission is particularly interested in policies, practices, research, and perspectives on issues of privacy and data access as they relate to the integration of large-scale human genome sequencing into research and clinical care. To this end, the Commission is inviting interested parties to provide input and advice through written comments.

Among other issues, the Commission is interested in receiving comments on the implications of large-scale human genome sequencing for the privacy of individuals, research subjects, patients and their families; the views of those groups and medical professional communities about privacy, both as regards genomic information and evolving notions of privacy, as evidenced and influenced by social media; and models and mechanisms for protecting privacy, in both genetic/genomic databases and biobanks, but also in large databases of sensitive information. The Commission is further interested in receiving comments on issues related to balancing individual and societal interests with regard to the sharing of and access to large-scale human genomic data; the views of patients and other stakeholders on who should have access to these

data and who should control access; models and mechanisms for governing access to genomic information; the role of health information technology in providing and governing access to genomic data; and access to genetic/genomic information by law enforcement entities.

Please address comments by e-mail to info@bioethics.gov, or by mail to the following address:
Public Commentary, The Presidential Commission for the Study of Bioethical Issues, 1425 New York Avenue, NW, Suite C-100, Washington, DC 20005. Comments will be publicly available, including any personally identifiable or confidential business information that they contain. Trade secrets should not be submitted.

Dated: March 21, 2012

Wanda K. Jones

Principal Deputy Secretary for Health, Department of Health and Human Services

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